PATENT Docket No.: 1662/49502

IN THE <u>UNITED STATES PATENT AND TRADEMARK OFFICE</u>

APPLICANT

SINGER ET AL.

SERIAL NO.

09/552,485

FILING DATE

April 18, 2000

**FOR** 

NOVEL SYNTHESIS AND CRYSTALLIZATION OF

PIPERAZINE RING-CONTAINING COMPOUNDS

GROUP ART UNIT:

1624

**EXAMINER** 

K. Habte

Address to:

**Assistant Commissioner for Patents** 

Washington D.C. 20231

## **DECLARATION OF CLAUDE SINGER**

I, CLAUDE SINGER, Ph.D., of David Elazar 8/8 Kfar-Sava Israel, having been warned that I must state the truth or be liable to the penalties prescribed by law for failure to do so, declare as follows:

- 1. I have worked for Teva Pharmaceutical Industries, Ltd ("Teva") since September 1, 1986. Since then I have been a project coordinator for generic drugs. I received a Ph.D. degree from the Polytechnic Institute Bucharest in 1985. As project coordinator in the development of technologies for synthetic drugs I have supervised the development of new methods for the synthesis of drugs and the discovery of new polymorphic forms for these drugs by crystallization. precipitation and other techniques. Since 1972 I have coordinated more than 40 projects including substances from very different classes.
- I conducted an experiment in which an adduct of mirtazapine and water was 2. prepared according to Example 6 of the above-captioned application, which states,

in relevant part, the following:

Mirtazapine (20 g), obtained as in Examples 2 and 3, is suspended in 20 mL of ethanol and heated to reflux. At reflux, 40 mL of water is added dropwise to the solution over one hour followed by cooling to 10° C. The resulting filter cake is washed with a solution of water:ethanol (2:1) and dried at 60° C under a vacuum.

- 3. I have read and understood the two Aronhime Declarations filed concurrently herewith and which reference the experiment described in the preceding paragraph. These two declarations accurately describe the experiment I conducted.
- 4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and believe are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:	Signed	
	Claude Singer, Ph.D.	

